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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/633,573	08/04/2000	Wilson T. Asfora	00-0050	2575

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EXAMINER

MAYNARD, JENNIFER J

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/633,573	ASFORA, WILSON T.
	Examiner	Art Unit
	Jennifer J Maynard	3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 09 December 2002.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-12 and 33-41 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 and 33-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION*****Response to Amendment******Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 and 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A).

Landy et al. discloses an intracranial pressure monitoring probe comprising a tubular portion (i.e. hollow shaft) (11) with a threaded portion (26) enabling the tubular portion to extend through all three layers of a patient's skull, a t-connector (50) provides an interface between the tubular portion and a tube (51) allowing fluid communication between the inside of the skull (i.e. subarachnoid space) and a pressure transducer (54), and a wrench or screwdriver (46) with radially extending wings (i.e. handles) (48) provides a mechanism for installing the tubular portion in the patient's skull.

Landy et al. fails to disclose the tubular portion having an integral pair of outwardly extending wings for facilitating finger rotation of the threaded tubular portion.

Miller et al. disclose an apparatus for monitoring local cerebral physiology comprising a subarachnoid bolt (11) defined as a hollow, threaded tubular portion with outwardly extending

wings, which allows the neurosurgeon to torque the bolt into a secure position within the thickness of the cranium, see Column 8, lines 60-63.

It would have been obvious to one having ordinary skill in the art to have modified Landy et al.'s tubular portion with unitary constructed wings associated therewith as taught by Miller et al. so as to eliminate the need for an additional or separate tool to torque the threaded tubular portion into the patient's skull.

Landy et al. in view of Miller et al. fail to disclose the retaining means on the exterior surface of the tubular portion adjacent the distal end for engaging an interior surface of a conduit.

Magram discloses a cannula for draining cerebrospinal fluid from the ventricle of a brain comprising a hollow tubular portion (156, 170) (see Figures 15 and 16) with retaining means (175) (see Column 5, lines 4-16) on the exterior surface thereof for engaging an interior surface of a conduit (152).

It would have been obvious to one having ordinary skill in the art to have modified Landy et al. in view of Miller et al.'s tubular portion with the retaining means taught by Magram (see Figure 16) so as to provide an integral mechanism for connecting the tubular portion to a tubular extension for remotely monitoring intracranial pressure, which is viewed as an art equivalent alternative to the t-connector disclosed by Landy et al..

Claims 1-6 and 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A).

Miller et al. disclose an apparatus for monitoring local cerebral physiology comprising a subarachnoid bolt (11) defined as a hollow, threaded tubular portion with outwardly extending

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wings, which allows the neurosurgeon to torque the bolt into a secure position within the thickness of the cranium, see Column 8, lines 60-63.

Miller et al. fails to teach the tubular portion comprising a retaining means.

Magram discloses a cannula for draining cerebrospinal fluid from the ventricle of a brain comprising a hollow tubular portion (156, 170) (see Figures 15 and 16) with retaining means (175) (see Column 5, lines 4-16) on the exterior surface thereof for engaging an interior surface of a conduit (152).

It would have been obvious to one having ordinary skill in the art to have modified Miller et al.'s tubular portion with a retaining means such as that taught by Magram so as to provide an art equivalent, alternative mechanism for connecting the tubular portion to a tubular extension thereby providing fluid communication between a remote transducer and the subarachnoid space thus allowing for the monitoring of intracranial pressure. (*see Landy et al. (US 4,600,013 A) for art relating to a device for monitoring intracranial pressure via a remote pressure transducer*)

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Knute et al. (US 4,903,707 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a drill bit for forming an opening, a stop collar selectively lockable in a position on the drill bit for setting a maximum penetration of the drill into a surface, and a conduit having first and second ends, the

first end adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative source.

Knute et al. discloses a kit for mounting a ventricular catheter assembly comprising a drill bit (81), a stop collar (83) and a conduit (19).

It would have been obvious to one having ordinary skill in the art to have modified the kit disclosed by Landy et al. in view of Miller et al. and further in view of Magram with the drill bit, stop collar and conduit taught by Knute et al., so as to provide means for penetrating the skull of a patient for subsequent placement of the evacuating port device, to limit penetration of the drill bit thus preventing trauma to brain tissue adjacent the skull, and to provide means for draining fluid causing high intracranial pressure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Lake (US 3,766,910 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Landy et al. in view of Miller et al. and further in view of Magram, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), and further in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Baudino (US 6,110,155 A).

Landy et al. in view of Miller et al. and further in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore (24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al. and further in view of Magram, by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Landy et al. (US 4,600,013 A) in view of Miller et al. (US 5,579,774 A), further in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A).

Landy et al. in view of Miller et al., further in view of Magram, and further in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Landy et al. in view of Miller et al., further in view of Magram, and further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Knute et al. (US 4,903,707 A).

Miller et al. in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a drill bit for forming an opening, a stop collar selectively lockable in a position on the drill bit for setting a maximum penetration of the drill into a surface, and a conduit having first and second ends, the first end adapted for connection to the subdural evacuating port device, the second end of the conduit being for connection to a negative source.

Knute et al. discloses a kit for mounting a ventricular catheter assembly comprising a drill bit (81), a stop collar (83) and a conduit (19).

It would have been obvious to one having ordinary skill in the art to have modified the kit disclosed by Miller et al. in view of Magram with the drill bit, stop collar and conduit taught by Knute et al., so as to provide means for penetrating the skull of a patient for subsequent placement of the evacuating port device, to limit penetration of the drill bit thus preventing trauma to brain tissue adjacent the skull, and to provide means for draining fluid causing high intracranial pressure.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Lake (US 3,766,910 A).

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Miller et al. in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a retractor for spacing sides of an incision in a scalp away from each other.

Lake discloses a disposable delicate tissue retractor comprising a pair of arms (12, 80) each having a proximal ends (no reference numeral; see Figures 2 or 9) joined together to form an apex, each of the arms extending away from the apex such that distal ends (no reference numeral; see Figures 2 and 9) of the arms are spaced from each other, the arms of the retractor forming a substantially V-shaped configuration.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space as taught by Miller et al. in view of Magram, by incorporating a retractor such as that which is taught by Lake, so as to allow for exposure of an adequate operative field to aid in proper placement of the subdural evacuating port in the patient's skull.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), as applied to Claims 1-6 above, and further in view of Baudino (US 6,110,155 A).

Miller et al. in view of Magram disclose the kit for evacuating a collection of fluid from a subdural space with the exception of a negative pressure device for creating a negative pressure condition.

Baudino discloses a catheter (14) for conducting fluid to or from the human body comprising a distal end (18) received in an opening (22) formed in a patient's skull and in a bore

(24) formed in the patient's brain tissue (28), a plurality of fluid apertures (32) are provided adjacent the distal end, and a source of negative pressure (no reference numeral; see Column 3, lines 27-30) can be applied to the proximal end (16) of the catheter to withdraw fluid from the area adjacent to the implanted, distal end.

It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Miller et al. in view of Magram, by incorporating a negative pressure device as disclosed by Baudino, so as to provide means for draining fluid causing high intracranial pressure.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 5,579,774 A) in view of Magram (US 5,913,852 A), and further in view of Baudino (US 6,110,155 A), as applied to Claim 11 above, and further in view of McNeil et al. (US 4,828,546 A).

Miller et al. in view of Magram, and further in view of Baudino discloses the kit for evacuating a collection of fluid from a subdural space with the exception of the negative pressure device comprising a Jackson-Pratt bulb.

McNeil et al. discloses a bulb evacuator for closed wound suction comprising an interior, a primary opening (20, 21) and a secondary opening (24) providing communication between the interior and an exterior of the bulb, a check valve (23) in communication with the primary opening for resisting exit of fluid from the interior of the bulb to the exterior of the bulb while permitting fluid flow into the interior through the primary opening, and a cap (25) for selectively closing the secondary opening of the bulb.

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It would have been obvious to one having ordinary skill in the art to have modified the kit for evacuating fluid from a subdural space taught by Miller et al. in view of Magram, and further in view of Baudino, by incorporating a bulb evacuator as disclosed by McNeil et al., so as to provide adaptable means for draining fluid causing high intracranial pressure which is characterized by its ease of operation.

***Response to Arguments***

Applicant's arguments with respect to claims 1-12 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer J Maynard whose telephone number is 703.305.1356. The examiner can normally be reached on Mondays-Fridays 9:30 AM-5:30 PM; 1st Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703.308.3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703.872.9302 for regular communications and 703.872.9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0858.

J Maynard *JM Maynard*  
February 24, 2003

*Brian L. Casler*  
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